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- 97. The isolated polynucleotide segment of claim 83, wherein the first polynucleotide sequence hybridizes under stringent conditions to a third reference polynucleotide having the position 1 to 579 sequence of SEQ ID NO:1.
- 98. A vector comprising the recombinant polynucleotide segment of Claim 70.
- 99. A recombinant expression system comprising an isolated host cell or non-human animal transformed with the recombinant polynucleotide segment of Claim 70 to express the recombinant polynucleotide segment.
- 100. A process for producing a Xanthine phosphoribosyl transferase polypeptide of the encoding polynucleotide sequence comprising the step of culturing a host cell of claim 99 under conditions sufficient for the production of said polypeptide, which is encoded by the recombinant polynucleotide segment.
- 101. The polynucleotide of claim 83, 85, 92, 93, 95 or 96, wherein said polynucleotide encodes Xanthine phosphoribosyl transferase polypeptide that is involved in the catabolism of nitrogenous metabolites. --

REMARKS

In view of the foregoing amendments and following response, Applicant believes that both the amended claims and the new claims presented herein are allowable. Reconsideration and allowance is respectfully requested.

By the present Amendment, new claims 83-101, directed to Group I, are presented. This Amendment presents for fee purposes, 33 claims, including 4 independent claims and 1 multiple dependent claim. Prior to this Amendment, fees for a total of 61 claims, including 7 independent claims and 1 multiple dependent claim had been paid for. In view of the cancellation of claims 21-23, 27, 43, 47, 52-67 and 74-82 without prejudice, Applicant respectfully submits that no



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additional fees are required by this Amendment. However, if any fees are due in connection with this Amendment, Applicant hereby authorizes the Commissioner to charge such fees to Deposit Account No. 50-0258.

The Applicant has cancelled claims 21-23, 27, 43, 47, 52-67, and 74-82 without prejudice or disclaimer of the subject matter therein. Moreover, the Applicant reserves the right to prosecute, in one or more patent applications, the cancelled claims, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification. Any amendments made herein to the claims were made to solely expedite or otherwise facilitate prosecution and were not made nor should they be construed to have been made to overcome any issue of unpatentability of the claims as they existed prior to such amendments.

#### **Support**

The specification has been amended to correct obvious typographical errors. Applicant respectfully submits that no new matter is introduced by these amendments.

The claims have been revised to clarify the invention. Support for the new claims, Applicant respectfully submits, can be found, for example, in the specification on pages 9-24. The new claims are directed to the invention in Group I (claims 1-11) and, Applicant respectfully submits, introduce no new matter. Support for the recitation of sequence relatedness can be found, for example, in the text in the portion of the Glossary directed to "IDENTITY" at pages 9-10, and this support is discussed below with reference to rejections under 35 U.S.C. §112. Claim 84 finds support, for example, at page 20, lines 17-21. The recitations with respect the mature polypeptide in claim 93 finds support, for example, at page 7, lines 4-6. The recitation of 30 contiguous nucleotides in claim 108 finds support at page 22, line 19. Claim 84 finds support, for example, at page 20, lines 17-21. Claim 112 finds support, for example, at page 6, lines 4-7.

#### **Restriction Requirement**

Applicant affirms the provisional election of Group I. While the election of Group I was without traverse, Applicant reserves the right to disagree with the restriction requirement applied to non-elected groups.



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### **Claim Objections**

Prior claim 51 is objected to as being an improper multiple dependent claim and claims 24-26, 36, 38-42 and 68-73 are objected to as being dependent upon a rejected base claim. Applicant respectfully submits that these objections have been overcome by the presentation of the revised claims.

### **Claim Rejections Under 35 U.S.C. §112**

Claims 21-23, 27, 43, 47, 52-67, and 74-82 have been canceled without prejudice and new claims 83-101 are presented herein. Applicant believes that these new claims obviate all §112 grounds of rejection raised by the Examiner.

Prior claims 1-3 and 7-10 stood rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter of the invention and under 35 U.S.C. §112, first paragraph, as lacking sufficient written description in the specification so as to enable one skilled in the relevant art to make and/or use the invention.

The Office Action avers that the recitation of “70% identity” in these claims is allegedly indefinite and not sufficiently described in the specification. Specifically, the Office Action alleges that these claims lack a detailed teaching to determine percent identity of a given sequence comparison. Applicant respectfully disagrees with such an assertion as supported by the following discussion.

First, Applicant respectfully points out that the Applicant’s claims are founded on a concrete boundary of relatedness to certain reference sequences. Further, in the “IDENTITY” portion of the Glossary at pages 9-10 and in the “Polynucleotides” Section at page 21, lines 9-20, of the specification, Applicant teaches how to determine identity of variant polynucleotides and polypeptides. Applicant has provided a detailed definition, including an explicit illustrative example, of the concept of percent identity which is set forth at page 9, line 15 et seq. of the specification. The definition of “IDENTITY” references the GCG program. See specification, for example, at page 9, line 20. It is well known in the art that the GCG program package comes with default parameters to determine sequence identity.



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Further, the specification also provides an example of how 95% identity of a polynucleotide or a polypeptide can be calculated. See specification, for example, at page 9, line 24 through page 10, line 17. This example recites a procedure that is straightforwardly algebraic, and requires no parameters. The language in the example directly implies the algebraic formula found in some of the rejected claims. In other words, the example and the formula call for one to find in the first polynucleotide sequence all of the sequence matching the reference sequence, and then any insertions, deletions or otherwise replaced residues directly imply a reduction in identity. There is unequivocally nothing indefinite about this calculation.

Moreover, the Applicant teaches, at page 9, lines 16-17, that preferred methods to determine identity are designed to give the largest match between the sequences tested. This teaching clearly indicates to those skilled in the art to calculate identity from the alignment that gives the largest match between the sequences tested. The level of skill among artisans practicing recombinant DNA technology is high and such highly skilled artisans would understand how to make the comparisons set forth in the claims, which comparison is independent of the method used.

Furthermore, Applicant respectfully submits that to satisfy the "how to make" requirement of 35 U.S.C. §112 one need only show how to make each embodiment claimed. The Applicant need not show that each and every embodiment can be made in any specified period of time or that all or a substantial portion of the embodiments have been made.

However, in seeking to have the allowance of the application and without conceding the validity of the rejection, the claims at issue have been revised to still more clearly define the invention. The recitations regarding sequence relatedness and identity determination in the revised claims find support in the Glossary section directed to "IDENTITY" at pages 9-10 and in "Polynucleotides" section at page 21 lines 9-20 of the specification. In particular, the language in the illustrative example at page 9, line 24 through page 10, line 5 directly implies the recital found in the following claim text:

a first polynucleotide sequence, or the complement of the entire length of such first polynucleotide sequence, wherein the first polynucleotide sequence is (a) a reference sequence that encodes the amino acid sequence set forth in SEQ ID

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NO:2, or (b) is identical with the reference sequence except that, over the entire length corresponding to the reference sequence, the nucleic acid sequence has an average of up to thirty substitutions, deletions or insertions for every 100 nucleotides of the reference sequence.

In other words, the identity determination calls for one to find in the prospective first polynucleotide sequence all of the sequence matching the reference sequence, and then any insertions, deletions or otherwise replaced residues directly create non-matches which take the prospective first polynucleotide sequence towards (or over) the metes and bounds established by the claim. The determination is totally independent of correction factors such as the "gap penalty" used in some procedures to calculate "percent identity." This language, Applicant respectfully submits, is not ambiguous.

Based on the above discussion, Applicant respectfully submits that the specification sufficiently describes the instant invention, as presently claimed, so as to allow one skilled in the art to readily determine the sequence relatedness between the claimed polynucleotide sequences and the reference sequences.

Accordingly, Applicant respectfully submits that that the revised claims overcome the Examiner's concerns under § 112, first and second paragraphs discussed herein regarding percent identity. Reconsideration and withdrawal of the rejection are requested.

Prior claims 21-23, 27-35, 37, 43-50, 52-67 and 74-82 stood rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not sufficiently described in the specification so as to reasonably convey to one skilled in the art that the Applicant was in possession of the claimed invention.

In particular, the Office Action posits that the specification fails to provide representative species of the genus of polynucleotides having 70% or more identity to a generic polynucleotide encoding a polypeptide having the amino acid sequence of SEQ ID NO:2. The Office Action further posits that the specification fails to describe identifying characteristics of the claimed polynucleotides species. For the reasons set out below, Applicant respectfully traverses.



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Applicant respectfully points out that the specification does indeed reasonably teach the claimed invention so as to convey with reasonable clarity to those skilled in the art that the Applicant was in possession of the invention at the time the application was filed.

For example, the Applicant does reasonably teaches various Xanthine phosphoribosyl transferase polypeptides other than that set forth in SEQ ID NO:2 at page 17, line 13 through page 18, line 10, and page 20, line 30 through page 21, line 20 of the specification. Further, for example, at page 16, line 8 through page 17, line 31 of the specification, the Applicant teaches how to obtain such sequences and their structure. As to identifying characteristics, Applicant respectfully points out that the specification reasonably teaches by which to identify various polynucleotide species. See, Applicant's teachings, for example at page 18, lines 11-17.

Furthermore, Applicant respectfully submits that to satisfy the "written description" requirement of 35 U.S.C. §112 one need only show with reasonable clarity to those skilled in the art. M.P.E.P. §2163.

Moreover, Applicant respectfully submits that given the sufficient description in the specification and the powerful tools available to molecular biologists at the time of filing, including tools to combinatorially create variations of the sequences set forth in this Application, one skilled in the art would be able to recognize various polynucleotides claimed by the Applicant. Similarly, given the description in the specification, determining, for example, an activity such as Xanthine phosphoribosyl transferase activity of the various polynucleotide species does not, Applicant respectfully submits, present an obstacle. Accordingly, Applicant respectfully submits that a skilled artisan can readily ascertain the invention to the scope claimed and requests reconsideration and withdrawal of the rejection as it might be applied to the revised claims.

In view of the foregoing and the new claims presented herein, Applicant respectfully requests that the Examiner reconsider withdraw the rejections under 35 U.S.C. §112, first and second paragraphs.



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**Allowable Subject Matter**

Applicant gratefully acknowledges the notation that prior claims 21-35, 43, 47 and 52-82 contained subject matter allowable over the prior art. In light of the above discussion and amendments, Applicant respectfully submits that all of the present claims are in condition for allowance, which allowance is earnestly solicited.

**Closing Remarks**

The Applicant thanks the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reexamination, reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

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